In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 16-878V

(to be published)

DOUGLAS KELLY,	*	
	*	Chief Special Master Corcoran
Petitioner,	*	Filed: October 18, 2021
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Renee Gentry, Vaccine Injury Litigation Clinic, George Washington University Law School, Washington, DC, Petitioner.

Adriana Teitel, U.S. Dep't of Justice, Washington, DC, Respondent.

ENTITLEMENT DECISION[1]

On July 25, 2016, Douglas Kelly filed a petition seeking compensation under the National Vaccine Injury Compensation Program ("Vaccine Program"),[2] alleging that his unilateral sensorineural hearing loss ("SNHL") was caused by an influenza ("flu") vaccine received on September 7, 2015. Petition (ECF No. 1) at 1. He has since refined his claim to allege that the

[1] This Decision will be posted on the Court of Federal Claims' website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means that the Decision will be available to anyone with access to the internet.** As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its current form. *Id*.

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-10–34 (2012) (hereinafter "Vaccine Act" or "the Act"). All subsequent references to sections of the Vaccine Act shall be to the pertinent subparagraph of 42 U.S.C. § 300aa.

flu vaccine significantly aggravated a pre-existing condition (asymptomatic microvascular angiopathy), which subsequently prompted his SNHL. Motion for Ruling on the Record at 20–21 (ECF No. 58) ("Br.").

The matter was reassigned to me in early 2021, after the special master formerly presiding over it determined that the claim could be best resolved via ruling on the record. For the reasons set forth below, and after review of the complete file and all briefs offered in the matter, I deny entitlement. Petitioner has not established that he suffered from any preexisting condition that the flu vaccine *could* aggravate, and his causation theory was not otherwise preponderantly supported.

I. Factual Background

Vaccination and Acute Hearing Loss

Mr. Kelly (who was 63 years old as of the date of vaccination) had some earlier health issues but no noted prior history of hearing loss. Thus, more than a year before the relevant vaccination, at a May 1, 2014 annual exam, Petitioner's primary care provider, Dr. Ronald Colson, memorialized in the assessment section of exam record the existence of coronary artery disease and mixed hyperlipidemia (high cholesterol), but opined that Petitioner's receipt of statins and other over-the-counter medications would be sufficient for treatment. Ex. 10 at 25. Otherwise, there is nothing in the pre-vaccination medical record establishing that Petitioner was ever diagnosed with any kind of angiopathy.

Petitioner received the flu vaccine around 2:00 p.m. on September 7, 2015. Ex. 1 at 1 (Rite Aid prescription and receipt noting payment for the vaccine was processed at 2:11 p.m.). Later that evening, he presented to the Rose Medical Center Emergency Room ("ER"). Ex. 2 at 18. There, Mr. Kelly stated that "2 hours after [receiving his flu vaccine] he began having ringing in the left ear associated with some lightheadedness," and that he was now (seven hours later) "unable to hear out of the left ear." *Id.* Petitioner denied having confusion, headache, or any problem with his other ear. *Id.;* Ex. 3 at 27, 31–32. Short onset of hearing loss was also confirmed in a letter Petitioner wrote to a subsequent treater, otolaryngologist Dr. Owen Reichman, on December 9, 2015, stating that in fact the ringing in his left ear began 30 minutes after receiving the flu vaccine. Ex. 4 at 12.

The ER treaters present at the time discussed Mr. Kelly's symptoms with Dr. Judd Jensen, the neurologist on call. Ex. 2 at 21. Dr. Jensen advised them to proceed with a head computed tomography ("CT") scan, and a CT angiogram ("CTA") scan of Petitioner's head and neck, to

rule-out a basilar artery infarct.[3] *Id.* at 21, 91–93. The head CT, however, revealed "no acute intracranial abnormality," and at most "a few areas of ill-defined low density in the left parietal white matter [that] could represent small vessel ischemic changes of indeterminate age." *Id.* at 16, 92. The head CTA revealed no occlusion, significant stenosis, nor aneurysmal dilation in either the anterior or posterior circulation, and the neck CTA results also appeared normal. *Id.* Treaters thus determined that Mr. Kelly should be discharged, with instructions to follow-up with an ear, nose, and throat "(ENT") specialist. *Id.* However, Petitioner proved "unable to ambulate independently whatsoever secondary to lightheadedness," so he was instead admitted to the hospital for further evaluation, and it was recommended he receive a brain MRI to rule out a cerebellar infarct. *Id.*

The MRI procedure was immediately initiated but was not completed because Petitioner complained of difficulty breathing. Ex. 2 at 30. Nevertheless, the performing radiologist opined that there appeared to be "no acute signs for ischemia," although the use of contrast would have been needed to confirm this impression. *Id.* The initial plan was to obtain a second MRI during the morning of September 8, 2015, but then it was determined that a study with contrast was not clinically warranted. *Id.* at 30, 35, 42. The final MRI report for what had been able to be completed noted the result was normal, with no acute signs consistent with a stroke. *Id.* at 32, 89.

Mr. Kelly started steroids at the ER within hours of his hearing loss onset (Ex. 2 at 37), and continued with oral prednisone after his discharge. *Id.* at 88, 182. Upon admission to the hospital thereafter, Mr. Kelly was examined by hospitalist Dr. Hannah Lee in the early morning hours of September 8, 2015. *Id.* at 30, 32. The record from this exam indicates that Petitioner was "complaining of left-sided tinnitus and hearing loss with lightheadedness that occurred half an hour after his flu shot." *Id.* He denied having chest pain, shortness of breath, headache, or double vision before his symptoms started, although he recalled having some lightheadedness, dizziness, and loss of balance while in the ER. *Id.* Dr. Lee "suspect[ed] peripheral vertigo; Meniere['s] disease,"[4] but proposed that "to rule out cerebrovascular accident" a number of tests, including an EKG, would have to be performed. *Id.* at 32.

Later that same morning, Petitioner was seen by Dr. Jensen and Neurology Department Physician's Assistant Kori Leman. Pet. Ex. 2 at 33. Petitioner relayed a history (and in particular the hearing loss) consistent with what he had told prior treaters, and a physical exam revealed mild

[3] The basilar artery supplies the brain and brainstem, and infarct is the stopping "of blood supply to the posterior circulation or vertebrobasilar system of arteries to the brain." Asad Ikram & Atif Zafar, BASILAR ARTERY INFARCT (2012), https://www.ncbi nlm nih.gov/books/NBK551854/.

[4] Meniere's disease is also called *endolymphatic hydrops, labyrinthine hydrops,* and *recurrent aural vertigo.* DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 532 (33rd ed. 2020) ("DORLAND'S"). It includes hearing loss, tinnitus, and vertigo resulting from non-suppurative disease of the labyrinth with edema. *Id.*

loss of balance with Romberg test.[5] *Id.* at 39. PA Leman assessed him with "hearing loss, tinnitus, balance disturbance, without vertigo sensation, negative MRI for stroke, and normal vascular workup leads to differential of viral labyrinthitis vs. Meniere's," with a "lean towards labyrinthitis due to lack of vertigo." *Id.* at 42. Steroidal medications were prescribed and administered on September 8, 2015 at 12:30 p.m., and PA Leman proposed an audiology consult in a few weeks if hearing loss persisted, but otherwise concluded that "no further brain imaging was required from [a] neuro perspective." *Id*. Dr. Jensen concurred, opining that Mr. Kelly's symptoms were likely due to "viral or post-viral labyrinthitis with the acoustic portion of the 8th nerve more involved than the vestibular portion." *Id.*

Petitioner was discharged the next day, on September 9, 2015. Ex. 2 at 12, 82. One discharge summary form listed the following diagnoses or conditions: "1. Hearing Loss and Dizziness 2. Hypokalemia 3. Hyperglycemia [and] 4. Hyperlipidemia." *Id.* at 14. Other discharge paperwork listed "Primary Diagnosis: vertigo likely benign Position vertigo or Labyrinthitis; Secondary Diagnosis: Hearing loss." *Id.* at 82, 168. Both discharge documents encouraged Petitioner to pursue physical therapy and follow-up with audiology. *Id.* at 13, 82, 149, 175.

Confirmation of Hearing Loss

On September 10, 2015 (the day after discharge from the hospital), Mr. Kelly was seen by otolaryngologist Dr. Reichman at ENT Denver, P.C. Ex. 4 at 12, 20. Audiologic testing revealed mild sloping to profound SNHL in the left ear, and Dr. Reichman formally assessed Petitioner with SNHL. *Id.* at 12, 20, 22–23. The impression section of the relevant record indicates that Dr. Reichman informed Petitioner that sudden hearing loss is "usually autoimmune, viral or vascular in origin." *Id.* at 14, 22. He also stated that it was "not clear why this occurred after the flu shot but *may be related to activation of antibodies*," although in two-thirds of cases the loss would resolve. *Id.* at 16 (emphasis added). But because Mr. Kelly had experienced vertigo along with his hearing loss, Dr. Reichman predicted that he would likely not improve. *Id.*

Petitioner had a follow-up appointment with Dr. Reichman on September 24, 2015. Ex. 4 at 16. A repeat audiogram revealed some improvement, but in Dr. Reichman's view "probably not enough to make much of a difference," and Petitioner also continued to have some balance issues. *Id.* at 18–19, 21. Petitioner was encouraged to continue his walking program, taking care not to overdo things, and Dr. Reichman opined that Petitioner would see improvement in everything except for his hearing. *Id.* Mr. Kelly also saw Dr. Colson again on that same day. Ex. 10 at 16. Physical exam revealed that Petitioner's hearing was "intact to conversational voice both ears." *Id.*

[5] The Romberg Test has an individual stand with their feet close together and their eyes closed, where they are found to sway the body or fall, as a result of affects in the posterior columns. DORLAND'S at 1686.

Petitioner was to call or return if his symptoms worsened or persisted. *Id.* at 17.

On November 30, 2015, Petitioner saw Dr. Reichman again and underwent a third audiogram. Ex. 4 at 11, 13–15. Although it revealed no significant changes, Mr. Kelly did have better speech reception when compared to his September 24, 2015 study. *Id.* He also reported that his tinnitus and lightheadedness had improved, but he experienced periodic dizziness and lightheadedness with quick motion. *Id.* at 11. Dr. Reichman proposed that Petitioner should consider a hearing aid if he had "trouble with work as he starts to do more." *Id.*[6]

2016 Treatment and Beyond

On February 1, 2016, approximately five months after receiving the flu vaccine, Petitioner was seen again by Dr. Reichman and underwent another audiogram that demonstrated stability in his hearing loss. Ex. 4 at 3–4, 7. Dr. Reichman proposed several treatments to address the hearing loss, including devices, but Petitioner requested the opportunity to consider them. *Id.* at 5. Several months later, Mr. Kelly returned to Dr. Reichman in May 2016. *Id.* at 1. His audiogram was again consistent with profound hearing loss in the left ear, but demonstrated a slight improvement from the September 10, 2015 study, and Petitioner reported less vertigo. *Id.* The listed diagnoses for the visit were "sensorineural hearing loss, unilateral, with unrestricted hearing on the contralateral side" and "sudden idiopathic hearing loss, left ear." *Id.* The final audiogram filed in this case is from early 2017, and its findings were consistent with the prior results (e.g., showing stability in loss. Ex. 13 at 1.

The sole additional record bearing on the claim and filed in the matter is from 2019 (after the Petition's initiation), when Mr. Kelly underwent a repeat MRI at Maui Diagnostic Imaging, and it was interpreted by David Thoma, D.O. Ex. 35 at 1.[7] The MRI revealed "moderate periventricular and subcortical supratentorial variable white matter T2/FLAIR hyperintensities," and "normal flow voids in the major cerebral vessels and deep venous sinuses. Diffusion weighted imaging appears within normal limits without evidence of ischemia or acute infarction." *Id.* As a result of these findings, impressions from it were listed as "1. Moderate, multifocal white matter hyperintensities, probably small vessel ischemic changes; 2. Normal MR appearance of the internal auditory canals. Specifically, the 7th and 8th cranial nerves are without focal enhancing

[6] A month later, Petitioner corresponded with Dr. Reichman's office, asking that the clinical summary contained in his medical records be corrected to note that his hearing loss occurred the same day as vaccination rather than a week later. Ex. 4 at 10. He noted in the letter that his desire to make this change related in part to his intent to bring a vaccine injury claim. *Id.* Because, however, the medical record *overall* is consistent with Petitioner's requested change, I do not deem this otherwise litigation-oriented request to suggest anything improper about the change.

[7] It appears that Petitioner's primary causation expert, Dr. Carlo Tornatore, was the referring physician for the repeat MRI, although the record does not reveal Dr. Tornatore to have treated Petitioner otherwise.

mass or abnormal morphology." *Id.*

II. Expert and Treater Opinions

A. *Carlo Tornatore, M.D.*

Dr. Tornatore filed three reports in this matter on behalf of Mr. Kelly. Report, dated March 13, 2017, filed as Ex. 14 (ECF No. 22-2) ("First Tornatore Rep."); Report, dated December 31, 2019, filed as Ex. 31 (ECF No. 47-2) ("Second Tornatore Rep."); Report, dated July 26, 2020, filed as Ex. 37 (ECF No. 54-2) ("Third Tornatore Rep."). He also prepared a written response to questions posed to the experts by the special master previously presiding over this case. Response, dated October 19, 2020, filed as Ex. 40 (ECF No. 56-2) ("Tornatore Resp."). His opinion in this matter evolved somewhat over time, but he has ultimately opined that the flu vaccine exacerbated Petitioner's alleged pre-existing microvascular disease, resulting in a Type I hypersensitivity reaction in Petitioner's ear sufficient to cause his SNHL. Tornatore Resp. at 1.

Dr. Tornatore is a board-certified neurologist. *See* Ex. 15, dated March 13, 2017 (ECF No. 22-3) ("Tornatore CV"). He graduated from Cornell University with a Bachelor of Arts in Neurobiology, and attended Georgetown University Medical Center, where he received a Master of Science in Physiology. *Id.* at 2. He subsequently graduated from medical school at Georgetown University School of Medicine, completing a residency in the Department of Neurology at Georgetown University Hospital. *Id*. He also completed a fellowship in molecular virology at the National Institute of Health in Bethesda, Maryland. *Id.*

Dr. Tornatore has published multiple articles addressing cell biology and pathology of demyelinating disorders. Tornatore CV at 7–14. Currently, he serves as Professor and Chairman of the Department of Neurology at Georgetown University Medical Center, Chairman and Neurologist-in-Chief of the Department of Neurology at Medstar Georgetown University Hospital in Washington, D.C., and Executive Director of the Multiple Sclerosis Patient Centered Specialty Home. *Id*. Dr. Tornatore possesses demonstrated expertise in the evaluation of immunologic matters and their intersection with neurologic disease and injury, but is not an ear specialist, and he has done only minimal research into the function of vaccines, publishing on the rabies vaccine and an abstract on the human diploid cell vaccine and demyelination. *Id.* at 8, 13.

First Report

Dr. Tornatore's initial report included a summary of Mr. Kelly's medical history and

overall treatment for his hearing loss. *See* First Tornatore Rep. at 1–5. He particularly highlighted Dr. Reichman's speculation from September 2015 that "activation of antibodies" attributable to vaccination might explain the SNHL. *Id.* at 5. Dr. Tornatore did not, however, go into detail about Petitioner's medical history or alleged susceptibility for this kind of injury (although his initial opinion does point to Petitioner's purported preexisting conditions as helping to explain the injury, and so it does point toward where his expert opinion ultimately ended up).

To ground his theory, Dr. Tornatore provided a brief overview of the inner ear's anatomy and function. First Tornatore Rep. at 5–6. He noted that two inner ear components critical to hearing and balance (the cochlea[8] and the semicircular canals[9]) "share the same blood supply," provided by the Labyrinthine artery—and thus any occlusion/blockage or other "vascular event" impacting this artery could result in hearing loss or balance issues. *Id.* at 6. Indeed, Dr. Tornatore maintained, acute hearing loss was understood to potentially possess a "vascular etiology," and was associated with a risk of stroke. *Id.;* H. Lee, *Isolated Vascular Vertigo*, 16 J. of Stroke 124–30 (2014), filed as Ex. 43 on Oct. 19, 2020 (ECF No. 56-5) ("Lee"). Additional support for hearing loss being the product of vascular/ischemic injury was also provided by migraine research (although such research pertained to cerebral vessels rather than those in the ear). First Tornatore Rep. at 6–7; E. Piovesan et al., *Oscillucusis and Sudden Deafness in a Migraine Patient*¸ 61 Arq Neuropsiquiatr 848–50 (2003), filed as Ex. 16 on April 20, 2017 (ECF No. 25-1) ("Piovesan").

To explain how the flu vaccine might have caused sufficient vascular blockage/occluding to produce hearing loss, Dr. Tornatore emphasized the fact that "atherosclerotic disease is an inflammatory disorder of the vessel wall." First Tornatore Rep. at 7. Vaccines inherently activate the immune system, and in doing so can produce some initial inflammation. If that inflammation impacted vessel walls in the ear already narrowed due to preexisting disease, acute ischemia leading to hearing loss was likely, and could occur in reaction to a "relatively small inflammatory response." *Id.* Alternatively, the hearing loss could simply be due to some "non-vascular mechanism" involving the cochlear cells, although Dr. Tornatore did not expand on this possible mechanism. *Id.*

Dr. Tornatore offered no literature supporting this element of his opinion, however, beyond a paper discussing a possible autoimmune etiology for SNHL. J. Berrocal & R. Ramírez-

[8] The spirally wound tube, that resembles a snail shell that forms part of the internal ear. DORLAND'S at 373.

[9] There are three long canals "of the bony labyrinth of the ear, forming loops and opening into the vestibule by five openings; they lodge the semicircular ducts of the membranous labyrinth." DORLAND'S at 275.

Camacho, *Sudden Sensorineural Hearing Loss: Supporting the Immunologic Theory*, 111 Annals of Otology, Rhinology & Laryngology 989–97 (2002), filed as Ex. 18 on April 20, 2017 (ECF No. 25-3). He also reasoned that because SNHL was "a very rare event," the fact that this case (plus another dismissed several years ago)[10] both involved acute onset of SNHL after the flu vaccine could not be explained away as coincidence. First Tornatore Rep. at 7–8.

Mr. Kelly's own medical work-up after onset of his SNHL, Dr. Tornatore maintained, was consistent with the conclusion that the hearing loss occurred due to vascular injury. The CT scan performed at the ER on September 7, 2015, for example, demonstrated "changes that were consistent with small vessel stenosis/atherosclerosis from his history of hyperlipidemia." First Tornatore Rep. at 6. He also deemed the findings with respect to Petitioner's white matter to be likely consistent with what would have been seen "in the vasculature of the inner ear," although such scanning was not performed at the time of Petitioner's ER visit (or even proposed by initial treaters). *Id.*

Finally, Dr. Tornatore discussed Petitioner's acute onset, defending it as reasonably associated with vaccination only hours before. SNHL, he argued, could be mediated by a "Type I hypersensitivity" reaction in which B cells are stimulated to produce IgE antibodies in a rapid manner, usually in response to allergens (and hence associated with immediate reactions like anaphylaxis or asthmatic attacks). First Tornatore Rep. at 7; J. Bellanti, *Immunology IV: Clinical Applications in Health and Disease* 664–65 (4th ed. 2011), filed as Ex. 20 on April 20, 2017 (ECF No. 25-5). Type I hypersensitivity could further be divided into an immediate phase (occurring "minutes after exposure") versus a "late phase reaction" two to four hours post-exposure, and involved the kind of cytokine release associated with the initial innate immune response. Tornatore Rep. at 7.

Second Report

Dr. Tornatore's second report was twice the length of the first (likely due, as he expressly noted, to the fact that it had been determined by the prior special master presiding over this case that the matter was going to be decided on the papers rather than at hearing). Status Report (ECF No. 43). This report included an initial records review and personal credentials summary largely identical to the first (Second Tornatore Rep. at 1–6), along with a far more detailed causation opinion, aspects of which responded directly to points made by Respondent's two experts.

After some additional reiteration of points made in the first report about the anatomy of

[10] *Park v. Sec'y of Health & Hum. Servs.*, No. 13-275V, 2014 WL 6435819 (Fed. Cl. Spec. Mstr. Oct. 28, 2014) (dismissed on petitioner's motion for failure to obtain expert).

the ear, Dr. Tornatore again proposed that a "vascular etiology" for SNHL existed, but he now fleshed out in greater detail his prior contention that an "autoimmune event" could mediate the vascular injury producing the hearing loss. Second Tornatore Rep. at 8–9. In support of this concept, Dr. Tornatore cited an animal study that revealed how vaccination could induce an autoimmune form of hearing loss. *Id.* at 9–10; C. Arturo Solares et al., *Murine Autoimmune Hearing Loss Mediated by CD4$^+$ T Cells Specific for Inner Ear Peptides*¸ 113 J. of Clinical Investigation 1210–17 (2004), filed as Ex. 33 on December 31, 2019 (ECF No. 47-4) ("Solares") (researching whether "defined inner ear-specific proteins were capable of targeting T cell-mediated autoimmune hearing loss in mice"). Dr. Tornatore also noted that electronic databases confirmed amino acid sequence homology between components of the flu vaccine and peptides in the cochlear structures in the ear. Second Tornatore Rep. at 10–11. This, he maintained, established that molecular mimicry (the process of a vaccine or other chemical agent having similar peptide chains causing an activation of autoreactive T or B cells) might plausibly explain how the flu vaccine could precipitate the kind of injury necessary for an autoimmune form of hearing loss. *Id.* at 11.

Dr. Tornatore took specific issue with arguments made by Respondent's experts in their reports. First, he maintained (in reaction to Dr. Phillips) that it did not matter that there was not strong record evidence that Mr. Kelly had pre-vaccination vascular disease, since that condition was understood to be asymptomatic frequently right up to the point of acute clinical presentation. Second Tornatore Rep. at 12. He also defended the portion of his opinion proposing a hypersensitivity reaction, noting that it was not undercut by an absence of evidence that Petitioner had previously experienced no flu vaccine reaction, since it would be expected that an "anamnestic immune response"[11] could present acutely. *Id.* at 13. The reliability of an IgE-driven hypersensitivity reaction resulting in hearing loss was corroborated by Solares, which also established that it could occur in the absence of proof of a systemic response (which certainly did not occur in this case). *Id.* And the fact that treatments specific for allergic reactions, like steroids or antihistamines, proved unavailing in ameliorating Petitioner's symptoms was not dispositive, since the irreversible character of the hearing loss meant that inflammatory-limiting treatments could not be effective. *Id; see also* Third Tornatore Rep. at 3 (reiterating same point in reaction to Dr. Bigelow).

Dr. Bigelow's criticisms were also deemed by Dr. Tornatore to miss their mark. The possibility of a preexisting vessel occlusion was not in Dr. Tornatore's view diminished by the absence of other neurologic symptoms, since "the relevant inflammation is directly in the

[11] Anamnestic refers to anamnesis, or aiding the memory. DORLAND'S at 73. When the term is employed in connection with vaccination, it means "an acceleration of the immune attack due to sensitization," typically from prior exposure to the same vaccine or its antigenic components. *Hargrove v. Sec'y of Health & Hum. Servs.*, No. 05-0694V, 2009 WL 1220986, at *7 (Fed. Cl. Spec. Mstr. April 14, 2009).

cochlea/vestibular apparatus," and thus presumably confined there, with low likelihood of "other neurologic findings." Second Tornatore Rep. at 14. He reiterated the possibility of a fast anamnestic hypersensitivity response, and also offered additional support for how SNHL could be, as here, unilateral. *Id;* at 15; M. Kuhn et al., *Sudden Sensorineural Hearing Loss: A Review of Diagnosis, Treatment, and Prognosis*, 15 Trends in Amplification 91–105 (2011), filed as Ex. 34 on December 31, 2019 (ECF No. 47-5).

Epidemiologic evidence offered to show the flu vaccine was not likely to produce hearing loss was in Dr. Tornatore's estimation useless, since it could not rule out truly rare events. Second Tornatore Rep. at 14–15. And Dr. Tornatore deemed significant the fact that Respondent's experts had offered no other possible alternative explanation for Petitioner's injury, nor did the record itself suggest anything. *Id.* at 15.

Third Report

Dr. Tornatore's third report responded to additional criticisms lodged against him by Dr. Bigelow. He challenged Dr. Bigelow's contention that SNHL is not particularly rare, observing that literature filed by Dr. Bigelow undermined this suggestion. Third Tornatore Rep. at 1–2. Dr. Tornatore also offered more literature to bulwark the association between SNHL and vascular problems. *Id.* at 2; S. Merchant et al., *Pathology and Pathophysiology of Idiopathic Sudden Sensorineural Hearing Loss*, 26 Otology & Neurotology 151–60 (2005), filed as Ex. 38 on July 26, 2020 (ECF No. 54-3) (arguing "the hypothesis that idiopathic sudden sensorineural hearing loss may be the result of pathologic activation of cellular stress pathways involving nuclear factor-$_K$B within the cochlea"). And the hearing loss did not have to be complete to still possess a vascular etiology. Third Tornatore Rep. at 2.

Next, Dr. Tornatore attacked Dr. Bigelow's argument that the theory of a vascular etiology was undercut by a June 2019 MRI that revealed no middle ear changes or occlusion. In reaction, Dr. Tornatore proposed that it was uncommon for MRIs to detect these kind of ear abnormalities in patients with SNHL. Third Tornatore Rep. at 2; K. Jeong et al., *Abnormal Magnetic Resonance Imaging Findings in Patients with Sudden Sensorineural Hearing Loss*, 95 Medicine 1–5 (2016), filed on July 26, 2020 as Ex. 39 (ECF No. 54-4). And Dr. Tornatore again denied that bilateral loss was required for there to be an autoimmune etiology, while observing that Dr. Bigelow had seemed to concede that the speed of Mr. Kelly's post-vaccination onset was (all things being equal) consistent with the speed for a Type I hypersensitivity response generally. Third Tornatore Rep. at 3.

Dr. Tornatore deemed the "fundamental issue" separating his opinion from Dr. Bigelow's was the latter's failure to "follow simple rules of logic." Third Tornatore Rep. at 3. Dr. Bigelow

was opining *both* that the true cause of Petitioner's hearing loss was unknown—but also that the vaccine could not have caused it. This, in Dr. Tornatore's assessment, reflected an implicit bias against the possibility of causation, especially since literature supported the conclusion that (a) vascular events could explain SNHL, (b) favored treatments of it suggested it had some inflammatory-related pathogenesis, and (c) "an autoimmune etiology to hearing loss is a viable thesis," as reflected in literature filed by Respondent. *Id.* at 2–3.

Response to Special Master Questions

The final written submission prepared by Dr. Tornatore usefully summarized his opinion in this case, and provided some additional arguments relevant to it. He reiterated his opinion that Mr. Kelly had a preexisting but asymptomatic microvascular disease, and an acute Type I hypersensitivity reaction in the middle ear had caused "focal" injury to structures there located, resulting in SNHL. Tornatore Resp. at 1, 4. Dr. Tornatore readily admitted that his opinion required the determination that Petitioner first *possessed* this preexisting disease (specifically "labyrinthine artery occlusion"), adding that the record supported his conclusion. *Id.* Although the condition was not easily diagnosed (since Dr. Tornatore deemed it difficult to obtain MRI imaging for inner ear vessels), the record showed that Petitioner had "all the hallmarks" of it, given his age, the very fact of his acute hearing loss, and Dr. Reichman's speculations about vaccine causality. *Id.* at 4.

The proposed hypersensitivity reaction, moreover, was likely mediated by IgE—even though there was no evidence of a localized reaction at the site of vaccination. Tornatore Resp. at 1–3. To explain this disparity, Dr. Tornatore compared the injury in this case to Meniere's disease a/k/a "endolymatic hydrops," a condition of the inner ear (importantly, not middle as is contended here) that can produce hearing loss or dizziness/vertigo. An animal study had confirmed that an inner ear allergic reaction (reflected as a Type 1 hypersensitivity reaction) could be provoked with antigenic stimulation. Tornatore Resp. at 2; T. Takeda et al., *Type 1 Allergy-Induced Endolymphatic Hydrops and the Suppressive Effect of Leukotriene Receptor Antagonist*, 33 Otology & Neurotology 886 (2012), filed as Ex. 41 on Oct. 19, 2020 (ECF No. 56-3) (studying the effect of the allergic reaction of DNP-As antigen on guinea pigs' inner ear and the inhibition effects of leukotriene receptor antagonist) ("Takeda").

The same kind of provocation of Meniere's had also been demonstrated to be possible in humans via an allergic prick test, which resulted in acute symptoms manifestation of cochlear disease not limited to the site of provocation. B. Topuz et al., *Provocation of Endolymphatic Hydrops with a Prick Test in Meniere's Disease*, 24 Advances in Therapy 819–25 (2007), filed as Ex. 42 on Oct. 19, 2020 (ECF No. 56-4) (testing whether the antigenic challenge causing allergic reaction is a stimulative factor for an episode of endolymphatic hydrops, specifically in

Meniere's disease) ("Topuz"). Topuz, however, involved individuals with diagnosed or suspected Meniere's, who were moreover tested with skin pricks of allergens to which they had been determined to be atopic/allergic. Topuz at 820-21. Here, Dr. Tornatore did not deem absence of proof of a localized reaction to be especially significant, since the vaccine was intramuscularly administered, making it difficult to "see" evidence of reaction. Tornatore Rep. at 3.

Dr. Tornatore also again summarized his arguments for why treatment focused on the allergic nature of the reaction (steroids or antihistamines) would be ineffective in addressing the acute and largely-irreversible effects of the ischemic injury, which he noted would manifest in minutes. Tornatore Rep. at 3. He maintained that onsets of 30 minutes (as some records suggested had occurred) to one or two hours were all equally medically acceptable based on his proposed mechanism. *Id.* And he repeated his contention that (effectively under the concept of "challenge-rechallenge")[12] the sensitivity reaction that his theory embraced would require a first-time antigenic exposure, or "initial sensitization phase," for the second allergic reaction to occur as acutely and quickly as posited. *Id.* at 4.

B. *Douglas Bigelow, M.D.*

Dr. Bigelow, Respondent's primary expert, offered two written reports, and (like Dr. Tornatore) prepared answers to questions posed in this case by the prior special master presiding over it. Report, dated May 8, 2019, filed as Ex. C (ECF No. 38-1) ("First Bigelow Rep."); Report, dated April 6, 2020, filed as Ex. E (ECF No. 51-1) ("Second Bigelow Rep."); Response, dated October 18, 2020, filed as Ex. F (ECF No. 57-1) ("Bigelow Resp."). He disputed that the flu vaccine was responsible for Mr. Kelly's SNHL.

Dr. Bigelow is board-certified in otolaryngology and neurotology. See Ex. C, dated May 20, 2019 (ECF No. 38-1) ("Bigelow CV"). He graduated from Hamline University with a Bachelor of Arts in Chemistry, and attended University of Minnesota School of Medicine. *Id.* at 1. He completed residency in Otolaryngology-Head and Neck Surgery at Washington University, St. Louis. *Id.* He completed later programs at the Midwest Otologic Group in St. Louis for Otology, Neurotology, Cranial Base Surgery, doing the same at the University of Zurich. *Id.* Finally, a study of Gamma Knife Radiosurgery in Pittsburgh. *Id.* Currently, he serves as an Associate Professor in the Department of Otorhinolaryngology: Head and Neck Surgery at the University of Pennsylvania School of Medicine. *Id.* at 2. He also serves as the Director of the Division of Otology/Neurotology at the University of Pennsylvania Medical Center. *Id.* Dr.

[12] The "challenge-rechallenge" theory is a model where "a person (1) is exposed to one antigen, (2) reacts to that antigen in a particular way, (3) is given the same antigen again, and (4) reacts to that antigen similarly." *Nussman v. Sec'y of Health & Hum. Servs.*, No. 99-500V, 2008 WL 449656, at *9 (Fed. Cl. Spec. Mstr. Jan. 31, 2008).

Bigelow has given several presentations on otology and the causes there of. *Id.* at 5–11. Along with that he has published several peer reviewed articles on otology and its presentation of symptoms. *Id.* at 11–14. He also has non-peer reviewed articles, abstracts, editorials, reviews and chapters published. *Id.* at 14–18. Dr. Bigelow has had many years treating and examining otology and neurotology, but is not a vaccine specialist. *See generally id.*

First Report

Like Dr. Tornatore, Dr. Bigelow began his initial report with an in-depth evaluation of the Petitioner's medical history relevant to the case. *See generally* First Bigelow Rep. at 2–6. He deemed Mr. Kelly's onset (manifesting as left-sided tinnitus/hearing loss and lightheadedness) to have occurred within a half-hour of the vaccination, based on representations made at the ER by the Petitioner. *Id.* at 5, 9; Ex. 2 at 26, 32. Dr. Bigelow saw no evidence in the record of other contemporaneous symptoms (not counting the nausea and dizziness Petitioner displayed the next day, which Dr. Bigelow deemed consistent with Petitioner's presentation). First Bigelow Rep. at 5. Imaging results were inconclusive, and could not confirm or refute the possibility that some brain problem explained the Petitioner's symptoms. *Id.* at 5–6.

Based on the medical history, Dr. Bigelow accepted Petitioner's diagnosis of left-sided SNHL, noting that his course, treatment, and eventual progression toward an incomplete recovery was consistent with it—although he deemed the cause of Petitioner's injury to be idiopathic. First Bigelow Rep. at 6. SNHL, he explained, is often idiopathic, with no causal etiology ever obtained. *Id.* Petitioner's injury was likely the same—and Dr. Bigelow proposed this was largely the case because Mr. Kelly never received a full work-up that might explain the original/underlying cause. The initial, incomplete MRI scan he had received, for example, was in Dr. Bigelow's view inadequate to rule out brain lesions as potentially causal. *Id.* Dr. Bigelow also considered it significant that Petitioner's hearing loss was not responsive to steroids when they were administered promptly after the SNHL presented, noting this undercut any contention that an autoimmune process explained Mr. Kelly's injury. *Id.* at 8. The fact that his hearing loss never became bilateral was also inconsistent with an autoimmune etiology. *Id.*

Dr. Bigelow next addressed some general points bearing on SNHL. Contrary to Dr. Tornatore, Dr. Bigelow deemed sudden SNHL "a fairly common problem," pointing out that 66,000 cases of SNHL occurred annually, and that he himself saw "a number of patients every week" complaining of it. First Bigelow Rep. at 6; T. Alexander & J. Harris, *Incidence of Sudden Sensorineural Hearing Loss*, 34 Otology & Neurotology 1586–89 (2013), filed as Ex. C-01 on May 20, 2019 (ECF No. 39-1) ("Alexander & Harris"). Alexander and Harris observe that "the majority of cases are idiopathic, with a specific cause identified in fewer than 30% of patients presenting with SSNHL [sudden SNHL]." Alexander & Harris at 1586. Dr. Bigelow allowed

that SNHL could have a number of causes, including a vascular or autoimmune-driven source, although he maintained that in most cases it was reasonably considered idiopathic. First Bigelow Rep. at 7. He denied ever confronting a case in which a vaccine could explain the SNHL. *Id.* at 9.

Dr. Tornatore's specific opinion—that Petitioner's SNHL was due to preexisting vascular harm to the "wall of the labyrinthine artery" exacerbated by the flu vaccine—was attacked by Dr. Bigelow on several levels. For example, Dr. Bigelow questioned whether Petitioner had any preexisting vascular problem in the first place, noting that the primary evidence of this—the CT scan, which showed "some evidence of what is likely small vessel ischemic changes" in Petitioner's brain—was an "extremely common" imaging finding, especially as a patient ages, but no scientific or medical studies linked this finding to atherosclerosis of the labyrinthine artery. First Bigelow Rep. at 7. And the evidence Dr. Tornatore cited in this regard was in Dr. Bigelow's view unpersuasive. The Lee article dealt with hearing loss due to vertebrobasilar ischemia, a condition associated with neurologic findings before or at the time of SNHL, and often specifically attributable to blockage in the anterior inferior cerebellar artery (responsible for directing blood to much of the brain), and of which the Labyrinthine artery was a branch. Lee at 125; First Bigelow Rep. at 7. Thus, infarction/occlusion sufficient to produce hearing loss would invariably also cause neurologic findings absent herein. Dr. Bigelow in fact deemed Petitioner's presentation more consistent with a viral-caused labyrinthitis or Meniere's disease. First Bigelow Rep. at 7.

Other literature cited by Dr. Tornatore was no more helpful to his theory, in Dr. Bigelow's assessment. One article acknowledged not only that the pathologic findings from patients with SNHL were inconsistent with what was common in cases of arterial occlusion, but also that what was seen when a person experienced Labyrinthine artery occlusion was "fibrosis and ossification of the cochlea"—completely contrary to Petitioner's presentation or course. First Bigelow Rep. at 7; A. Belal, Jr., *Pathology of Vascular Sensorineural Hearing Impairment*, 90 The Laryngoscope 1838 (1980), filed as Ex. 17 on April 20, 2017 (ECF No. 25-2) ("Belal"). And findings relating to sudden hearing loss in a patient with migraines, like what was presented in Piovesan, had no relevance to this case, since Petitioner had no comparable history, and since the pathologic mechanism that led to hearing loss there was vasospasm[13] something not alleged to have occurred herein. Piovesan at 1832–35.

Dr. Bigelow flatly denied that any reliable medical or scientific literature existed that could link the flu vaccine to an inner ear vascular injury. First Bigelow Rep. at 8. Rather, he noted the existence of reputable and reliable epidemiologic evidence specifically relevant to

[13] Spasm of the blood vessels, resulting in vasoconstriction. DORLAND'S at 1997.

SNHL suggesting the contrary. *Id.* at 8–9; R. Baxter et al., *Sudden-Onset Sensorineural Hearing Loss after Immunization: A Case-Centered Analysis*, 155 Otolaryngology-Head and Neck Surgery 81–86 (2016), filed as Ex. C-04 on May 20, 2019 (ECF No. 39-4) ("Baxter") (researching connections between SNHL and vaccinations finding no evidence of increased risk). At most, there was some limited case report evidence of a connection, but the particular article identified by Dr. Bigelow was both distinguishable on the facts (it involved *bilateral* hearing loss that proved responsive to steroids) and also expressly acknowledged that causation could not be stated with certainty. H. Huang et al., *Bilateral Sudden Deafness Following H1N1 Vaccination*, 143 Otolaryngology-Head and Neck Surgery 849–50 (2010), filed as Ex. C-05 on May 20, 2019 (ECF No. 39-5) ("Huang") (subject's bilateral hearing loss occurring 14 hours after vaccination). Dr. Bigelow admitted the existence of some other case reports associating a live attenuated MMR vaccine with hearing loss.

The exceedingly-short post-vaccination timeframe in which Petitioner's SNHL manifested was also, in Dr. Bigelow's view, another factor eliminating the flu vaccine as potentially causal. Again, Dr. Bigelow noted the absence in this time period of other corroborative symptoms, like anaphylaxis, that would demonstrate the presence of an acute inflammatory reaction in response to vaccination and manifesting as a hypersensitivity reaction. First Bigelow Rep. at 8. The short timeframe was not consistent with an autoimmune reaction either, since it would take more than a day for even the most immediately-produced class of these autoantibodies, IgM, to appear. *Id.*

Second Report

Dr. Bigelow's next report was a detailed response to Dr. Tornatore's Second Report. He began by defending his contention that SNHL was common, noting that the primary article he offered to support this contention, Alexander and Harris, was a 2013 study, in comparison to the paper cited by Dr. Tornatore from 1996 (which in turn relief on 1973 data to establish the condition's rarity). Second Bigelow Rep. at 1; G. Hughes et al., *Sudden Sensorineural Hearing Loss*, 29 Otolaryngologic Clinics of North America 393–405 (1996), filed as Ex. 21 on April 20, 2017 (ECF No. 25-6) ("Hughes"); *see also* Kuhn at 91. Dr. Bigelow also opined that Petitioner was in the high risk group for SNHL given his personal demographics (male in mid-60s). Second Bigelow Rep. at 2.

Dr. Bigelow emphasized again his prior statements that SNHL was more often than not deemed idiopathic, rather than (as Dr. Tornatore opined) likely attributable to vascular or autoimmune injury (in the absence of proof structural defect to the ear). In so doing, he contested the extent to which some of Dr. Tornatore's literature actually supported his opinion, noting (for example) that Hughes agreed that "definitive proof" connecting SNHL to vascular problems was

lacking (although it still deemed it a reasonable hypothesis). Second Bigelow Rep. at 2; Hughes at 395. But a different article offered by Dr. Bigelow suggested that individuals diagnosed with SNHL possessed evidence of ear lesions inconsistent with a vascular cause. H. Schuknecht & E. Donovan, *The Pathology of Idiopathic Sudden Sensorineural Hearing Loss*, 243 Archives of Otorhinolaryngology 1–15 (1986), filed as Ex. E-02 on April 7, 2020 (ECF No. 51-3) ("Schuknecht & Donovan"). This article found that of the three most mentioned etiologies—vascular lesions, membrane breaks and viral infection—the third cause was best-supported from a scientific standpoint. Schuknecht & Donovan at 14.

Mr. Kelly's own medical history remained, in Dr. Bigelow's view, simply inconsistent with his having experienced hearing loss due to vascular harm, preexisting or not. The fact that his hearing loss was incomplete at all frequencies (being more severe in higher than low frequencies, as evidenced by testing performed approximately a year and a half after the vaccination) was not reflective of the degree of harm a vascular-caused injury would display, since the literature filed in the case suggested it would progressively lead to increased "fibrosis and ossification of the cochlea" over time. Second Bigelow Rep. at 3; Ex. 13 at 1.

Petitioner's MRI scans similarly did not corroborate Dr. Tornatore's contentions about a vascular etiology. Dr. Bigelow stated that any patient evaluated for SNHL would undergo MRI scanning, and in fact (and contrary to Dr. Tornatore's assumptions) the scan *would* be able to make out the cochlea and labyrinth in the ear, given the fluid found in each. Second Bigelow Rep. at 3.[14] As a result, if fibrosis or ossification were present, "there is a loss of the T2 signal in the cochlea on the MRI scan" and it would be readily ascertainable. *Id.* But the June 2019 MRI scan Petitioner underwent (and which Dr. Bigelow reviewed) revealed that Petitioner's "cochlea and labyrinth appeared perfectly normal," with no evidence of fibrosis, ossification, or other pathology (and none noted in the radiology report itself). *Id.*[15]

More specifically, Dr. Bigelow argued that the literature filed in support of a vascular etiology for SNHL in some cases only underscored why it was so unlikely given Petitioner's medical history. Although Lee did discuss sudden hearing loss in some individuals with vertebrobasilar ischemia but without concurrent neurologic issues, such cases were more commonly "associated with some neurologic findings"—findings completely absent here. Second Bigelow Rep. at 2; Lee at 125. Belal was a case report of two patients, one of whom had

[14] MRI or magnetic resonance imagining shows fluids by temporarily realigning water molecules in your body through the magnetic field. MAYO CLINIC, https://www.mayoclinic.org/tests-procedures/mri/about/pac-20384768 (last visited Sept. 26, 2021).

[15] Dr. Bigelow also noted that the MRI revealed no brain or nerve lesion explanation for the SNHL, underscoring its likely idiopathic nature. Second Bigelow Rep. at 4.

bilateral hearing loss while the other died of leukemia that was demonstrated to have infiltrated the patient's temporal bones—again, fact patterns easily distinguishable from Petitioner's history of unilateral hearing loss *not* accompanied by evidence of other illness. Second Bigelow Rep. at 2; Belal at 1836. Moreover, the Belal subjects demonstrated cochlea ossification thought to be the product of vascular occlusion, something not demonstrated herein. Second Bigelow Rep. at 2–3; *see also* Schuknecht & Donovan at 14 (deeming finding of fibrous tissue and bone in inner ear "presumptive evidence" that the hearing loss has a vascular etiology).

Dr. Bigelow also repeated his prior challenges to the contention that there could be an autoimmune etiology for Petitioner's SNHL. Individuals with SNHL caused by an autoimmune process typically present with *bilateral* hearing loss (or loss in one ear followed by loss in the other days to a few weeks later), but Mr. Kelly's hearing loss was confined to his left ear, and also did not feature the fluctuations common when the hearing loss was attributable to an autoimmune process. Second Bigelow Rep. at 3–5. Literature cited by Dr. Tornatore to support autoimmunity as a potential explanation was distinguishable, because the patients considered in the case reports mentioned therein *all* had been diagnosed with a systemic autoimmune disease, whereas Petitioner has never been. *Id*; B. Rossini et al., *Sudden Sensorineural Hearing Loss and Autoimmune Systemic Diseases*, 21 International Archives of Otorhinolaryngology 213 (2017), filed as Ex. 32 on Dec. 31, 2019 (ECF No. 47-3) ("Rossini"). Rossini purposefully looked at the connections between patients with sudden SNHL and a systemic autoimmune disease, specifically ruling out those without one, and thus clearly differentiating those circumstances from the Petitioner's. *See id.* Also, autoimmune-caused inner ear disease is typically responsive to steroids—a fact confirmed by Rossini. Second Bigelow Rep. at 3; Rossini at 217. But the record revealed that Petitioner had been given steroids within hours of his hearing loss and before his hospital discharge—but without benefit. Second Bigelow Rep. at 4. And the speed of Petitioner's hearing loss—30 minutes to two hours after vaccination—was not consistent with an autoimmune process, which would be dependent on a slower, adaptive immune response. Second Bigelow Rep. at 5.

Dr. Bigelow ended his second report by revisiting the evidence he maintained closed the door on the contention that the flu vaccine could precipitate SNHL, or did so here. Reliable epidemiologic evidence existed to rebut Petitioner's causation contentions. Baxter, for example, involved almost nine million vaccinations over a seven-year period, but found no increased risk in a case-controlled comparison.[16] Second Bigelow Rep. at 5; Baxter at 85. Moreover, had Mr. Kelly possessed some preexisting propensity for a hypersensitivity reaction to the vaccine, there would have been corroborative evidence of the reaction *itself,* in addition to the hearing loss.

[16] Case-control studies "compare[] a group with a disease or condition to a control group without the condition." *Snyder ex rel. Snyder v. Sec'y of Health & Hum. Servs.*, No. 01-162V, 2009 WL 332044, at *199 (Fed. Cl. Spec. Mstr. Feb. 12, 2009).

Second Bigelow Rep. at 5. Nor was there trustworthy evidence of a "challenge-rechallenge," based on the fact that Petitioner had received the flu vaccine in the past (and therefore was more susceptible to a rapid reaction in future encounters with it). Literature in fact supported the conclusion that revaccination with the flu vaccine led to fewer, not more, reactions. *Id*; Baxter at 85; J. Diez-Domingo et al., *Safety and Tolerability of Cell Culture-Derived and Egg-Derived Trivalent Influenza Vaccines in 3 to <18-year-old Children and Adolescents at Risk of Influenza-Related Complications*, 49 International J. of Infectious Diseases 174 (2016), filed as Ex. E-06 on April 7, 2020 (ECF No. 51-7).

Response to Special Master Questions

Dr. Bigelow's two-page letter responding to questions posed to him by the special master formerly presiding over this matter focused on a single issue: what other neurologic symptoms would accompany an "occlusion event" impacting the blood supply to the inner or middle ear, had Petitioner experienced one. Bigelow Resp. at 1. He noted several, including but not limited to vertigo, hearing loss, tinnitus, and facial numbness, as well as facial palsy, Horner syndrome[17], and hemiataxia.[18] *Id.* Mr. Kelly had displayed only the kinds of symptoms directly associated with the hearing loss (like dizziness or tinnitus), but did not reveal the other "central neurologic signs." *Id.*

In addition, Dr. Bigelow reiterated his prior assertion that none of the imaging or scans Petitioner had received—either at the time of the hearing loss or later—revealed brain lesions that would be consistent with occlusion. Bigelow Resp. at 2. While he acknowledged that an occlusion event isolated to the Labyrinthine artery (as somewhat alleged herein) would not necessarily be directly visible in such imaging, such an injury (had it occurred) would have so harmed both the relevant artery and cochlea more generally that the 2019 MRI Petitioner received "would have demonstrated significant loss of the T2 signal of the inner ear"—and yet it did not. *Id;* Ex. 35 at 1.

C. *Michael Phillips, M.D.*

Dr. Phillips, an allergist/immunologist, provided a single report for Respondent, although it was not referenced in Respondent's briefing. Report, dated August 12, 2017, filed as Ex. A (ECF No. 31-1) ("Phillips Rep."). Dr. Phillips opined that Petitioner's SNHL could not be linked

[17] Horner syndrome includes the symptoms of sinking of the eye and upper eyelid, elevation of the lower eyelid, constriction of the pupil, anhidrosis and flushing of the affected side of the face and narrowing of the palpebral fissure caused by a brainstem lesion. DORLAND'S at 1803.

[18] Hemiataxia is ataxia affecting one side of the body only. DORLAND'S at 825.

persuasively to the flu vaccine.

Dr. Phillips is board-certified in internal medicine along with allergy and immunology. Ex. A at 2, dated Jan. 2014 (ECF No. 31-2) ("Phillips CV"). He graduated with a Bachelor of Science degree from the University of Wisconsin, continuing his education at the University of Wisconsin School of Medicine. *Id.* at 1. Dr. Phillips completed a residency at the University of Pennsylvania and was a research fellow at Harvard Medical School. *Id.* He also completed research at the Walter Reed Army Institute of Research in the Immunology, Division of Communicable Diseases and Immunology. *Id*. Currently, Dr. Phillips serves as a Professor of Medicine in the Pulmonary Allergy Critical Care Division at the University of Pennsylvania School of Medicine, and is a Lead Clinical Physician at the University of Pennsylvania, Department of Medicine. *Id.* at 2. He is the Director of Allergy Services at the University of Pennsylvania and consults for the Philadelphia Veterans Administration Hospital. *Id.* at 2–3. Dr. Phillips has written over one hundred papers on subjects covering autoimmune reactions, neurological diseases, vaccination, and others. *Id.* at 5–13. He has also published several abstracts, editorials, reviews, chapters, and books on the same topics. *Id.* at 13–14. Dr. Phillips has had numerous years studying and researching allergy and immunology issues. *See generally id.*

Like the other experts, Dr. Phillips devoted part of his written report to a summary of Mr. Kelly's medical history, and it paralleled what Dr. Tornatore provided. Phillips Rep. at 4–6. However, Dr. Phillips questioned whether Dr. Tornatore's opinion was consistent with immunologic or epidemiologic principles. *Id.* at 7. First, he maintained that evidence of a preexisting vascular condition in Petitioner was absent. Any imaging evidence suggestive of vascular disease was not in the region of the ear, and he had demonstrated no stroke-oriented symptoms. *Id.* In addition, the statins he was taking for high cholesterol/hyperlipidemia seemed to be working, and there was in any event no correlation between hyperlipidemia and ear-oriented vascular disease. *Id.* Otherwise, the medical record showed nothing suggestive of an immune-oriented cross-reaction having occurred in the ear, and no serologic testing or imaging results supported such a conclusion either. *Id.* at 11.

Dr. Phillips next considered Dr. Tornatore's argument that an allergic reaction mediated by IgE could explain Petitioner's SNHL. He noted the general unlikeliness of this possibility, given that there was no evidence Petitioner had any preexisting allergy to the flu vaccine, and the record did not establish any other manifestations of an allergic reaction (e.g., hives, respiratory distress, edema, etc.). Phillips Rep. at 7. In addition, such a reaction would be "reversible by antihistamines and steroids," yet these treatments did not prove effective for Mr. Kelly, and none of his treaters otherwise proposed this explained his SNHL. *Id.*

More specifically, an IgE-mediated allergic reaction would require "the interaction of mast-cells[19] bearing IgE receptors for specific antigen," but no such antigen had been identified. Phillips Rep. at 7–8. And the reaction would inherently have a localized character before becoming sufficiently systemic to impact the ear—but Petitioner demonstrated no reaction on his arm or allergic-like injury there. *Id.* at 8. An IgE-mediated reaction would not otherwise result in "vascular obstruction" distant from the locus of the vaccine's administration. *Id.* at 8. There were other possible, non-IgE-mediated allergic reactions (such as a "leukotriene mediated delayed reaction"), but Dr. Phillips maintained they would take longer than thirty minutes to two hours to produce vasculitic-associated symptoms, and thus were inconsistent with Petitioner's short onset. *Id.*

An autoimmune-mediated form of hearing loss attributed to the flu vaccine was also rejected by Dr. Phillips. He allowed for the possibility of "reactions of the immune system to specific antigens in the cochlea" resulting in sudden hearing loss, and admitted that an autoimmune reaction resulting in "secondary vascular occlusion" produced by vasculitis was a reliable explanation for some forms of SNHL. Phillips Rep. at 8–9. But Dr. Phillips argued there was an absence of evidence that the flu vaccine could precipitate such a loss via molecular mimicry and a cross-reaction. Phillips Rep. at 8. Since the vaccine is routinely administered to millions of U.S. citizens each year, far more individuals should be experiencing hearing loss due to the vaccine than are reported, yet epidemiologic evidence undercut this conclusion. *Id.* at 8–9; Phillips Rep. at 9 (noting several studies that compared vaccinated versus un-vaccinated populations with no statistical difference in autoimmune vasculitis, a theory of SNHL).

One study referenced by Dr. Phillips was specific to the question of the role vaccines might play in causing SNHL. *See* Baxter (finding "no indication of an increased risk of immunization with any vaccine prior to the development of [sudden SNHL]"); Phillips Rep. at 10. Dr. Phillips emphasized his opinion that Baxter had statistical significance, showing only 0.965 odds of SNHL after vaccination. Phillips Rep. at 10. Thus, Dr. Phillips concluded that the existing epidemiologic evidence "clearly shows that there is no increased occurrence of vasculitis" that might result in SNHL, and he otherwise discounted the causal value of case reports. Phillips Rep. at 11.

III. Procedural History

After initiation of this claim in July 2016, Petitioner filed medical records through early 2017. Before then, Respondent filed a Rule 4(c) Report on October 11, 2016 (ECF No. 10),

[19] A mast-cell is a "type of migrant connective tissue cell with basophilic, metachromatic, cytoplasmic granules that contain histamine and heparin in humans and serotonin in species such as the rat and mouse." DORLAND'S at 315.

contesting entitlement. Petitioner thereafter filed the first expert report from Dr. Tornatore in March 2017, and Respondent in reaction filed Dr. Phillips's expert report in August of that same year. Additional rounds of expert reports were filed through the fall of 2020 (including the letter responses to questions posed by the special master formerly presiding over this case).

Petitioner first expressed a willingness to resolve the case via Ruling on the Record in a status report on August 5, 2019 (ECF No. 43). Petitioner then filed his Motion in December 2020, with Respondent opposing entitlement on March 9, 2021 (ECF No. 64) ("Opp."). In the intervening timeframe, the matter was reassigned to me. Petitioner completed briefing on the matter with a Reply filed April 12, 2021 (ECF No. 65) ("Reply").

IV. Parties' Respective Arguments

Petitioner's Brief

Petitioner argues that his preexisting, asymptomatic microvascular angiopathy was worsened by receipt of the flu vaccine, resulting in sudden onset of SNHL. Br. at 20–21. Prior to vaccination, he had risk factors for vascular disease from hyperlipidemia, taking medication for this, and no prior history of any hearing-related issues. Ex. 3 at 27, 31. After vaccination, however, he started experiencing severe tinnitus, imbalance with multiple falls, and lightheadedness. Br. at 9. Thereafter he could not walk without issues, was unable to drive, and ringing in his ears only stopped when he was asleep. *Id.*; Ex. 28 at 3. All of these health burdens took a significant toll on his life, greatly limiting what he was able to do day-to-day. Br. at 10.

In defense of causation, Petitioner maintains that Dr. Tornatore has demonstrated how the flu vaccine could provoke a Type 1 hypersensitivity reaction that significantly aggravated his pre-existing asymptomatic condition. Br. at 16. The theory is supported by animal models and human data collection demonstrating how an immune reaction or hypersensitivity may occur upon introduction of an antigen. Br. at 12; Ex. 20 at 1–2; Ex. 41 at 4. Alternatively, Petitioner identifies a vascular or autoimmune event as the cause. *Id.* at 11; Ex. 4 at 22; Ex. 14 at 5. Numerous items of literature cited by Dr. Tornatore show how the inner ear works and how its structures could have been restricted. Br. at 13–14. Dr. Tornatore also observed that while MRI evidence did not reveal inner ear abnormalities or other findings consistent with his theory, studies have shown that very few patients with SNHL show abnormalities in the first place. *Id.* at 14; Ex. 39 at 1. Also significant was the fact that Petitioner's treating physician, Dr. Reichman, proposed the SNHL could have been caused by the vaccination. Br. at 16–17. Finally, Petitioner maintains that the short onset (less than two hours) was consistent with filed literature and thus medically acceptable. Br. at 16–17.

Respondent's Opposition

Respondent argues for dismissal of the claim. Respondent accepts that Petitioner experienced SNHL, but maintains that the record does not support the conclusion that Petitioner had an asymptomatic microvascular disease. Opp. at 17–18. Even though Petitioner was receiving medication for hyperlipidemia, the condition was under control, and thus provides weak support for Petitioner's contention that he had a preexisting medical issue. *Id.* at 17. Otherwise, the medical records provide no evidence of any preexisting vascular condition, or an autoimmune etiology for his SNHL. *Id.* at 32–33; Ex. C at 7; Ex. E at 3. And Dr. Reichman's speculation of a vaccine association was ultimately not corroborated by the entire record. Opp. at 33; Ex. 4 at 22.

Respondent also notes that although Dr. Tornatore points to Petitioner's CT scan as evidencing "a few areas of ill-defined low density in the left parietal white matter [that] could represent small vessel ischemic changes of indeterminate age," this assertion lacks evidentiary strength. Opp. at 18; Ex. 2 at 16, 92. In addition, Dr. Tornatore's contention was not bulwarked with literature support, and Dr. Bigelow did not also deem any diagnostic evidence from the record as consistent with this conclusion. Response at 18; Ex. C at 6; Ex. E at 3.

More broadly, Respondent maintains that the claim of significant aggravation is untenable, noting that Petitioner's purported underlying vascular condition is incongruously alleged to have "caused or primed him to suffer an entirely separate condition as a result of his vaccine." Opp. at 19. Indeed, since Petitioner had admitted that his hearing was normal pre-vaccination, the onset of SNHL could inherently not have "aggravated" any absent preexisting hearing problem. *Id.*

Respondent otherwise acknowledges that aspects of Dr. Tornatore's causation theory have scientific or medical reliability, but that its components do not add up to preponderant evidence that the flu vaccine could cause SNHL under the facts of this case. Opp. at 22. For example, Dr. Tornatore relies upon a study relating to individuals with Meniere's disease, but that illness is not a product of issues with the arterial system of the inner ear (which is the alleged situs for injury in this case). *Id*. at 22–23. And two other studies he cites involved autoimmune-mediated SNHL—a causal mechanism distinguishable from the vascular etiologies his theory seemed to favor. *Id.* at 29. Respondent also noted the extent to which Dr. Tornatore's causation theories were inconsistently pursued, with him at some points claiming no Labyrinthine artery infarction was causal, while saying the opposite elsewhere. *Id.* at 30; Ex. 40 at 1,3–4; Ex. 31 at 14. Dr. Bigelow, by contrast, located no literature support for an association between the flu vaccine and SNHL. Opp. at 31–32; Ex. C at 8.

Petitioner's Reply

On reply, Petitioner reiterates his assertion that his history of hyperlipidemia is a risk factor for a vascular condition. Reply at 3; Ex. 31 at 8. Beyond that, Petitioner's medical records contain evidence that also establish the presence of a microvascular disease, like the CT scan emphasized by Dr. Tornatore. Reply at 4; Ex. 3 at 31–32. Even the June 2019 MRI is supportive, since, Petitioner argues, it reveals "probable small vessel ischemic changes." Reply at 4; Ex. 35 at 1.

Petitioner also maintains that Dr. Tornatore's theory was biologically plausible. Reply at 6; Ex. 40 at 2. Literature filed in support demonstrated that a "systemic immune challenge resulted in a focal inner ear type I hypersensitivity reaction within 1 hour after the immune challenge." Reply at 7. And the possible injury mechanisms Dr. Tornatore proposed are generally accepted in the medical community. *Id.* at 8. In effect, Petitioner maintains, Respondent is demanding medical certainty for causation, even though that is not the proper evidentiary standard. *Id.* at 9. Finally, Petitioner observed that there was no other possible cause for his SNHL (and Respondent offered nothing in the alternative), and that he was able to demonstrate treater support for causation. Reply at 10–11. Finally, the short onset timeframe (two to four hours) was consistent with literature and otherwise medically acceptable. *Id.* at 12.

V. Applicable Law

A. *Standards for Vaccine Claims*

To receive compensation in the Vaccine Program, a petitioner must prove that: (1) they suffered an injury falling within the Vaccine Injury Table (i.e., a "Table Injury"); or (2) they suffered an injury actually caused by a vaccine (i.e., a "Non-Table Injury.) *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano*, 440 F.3d at 1320. In this case, Petitioner does not assert a Table claim.

For both Table and Non–Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (explaining that mere conjecture or speculation is insufficient under a preponderance standard). On one hand, proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). But on the other hand, a petitioner

must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non–Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health and Hum. Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury." Each *Althen* prong requires a different showing and is discussed in turn along with the parties' arguments and my findings.

Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

However, the Federal Circuit has *repeatedly* stated that the first prong requires a preponderant evidentiary showing. *See Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1360 (Fed. Cir. 2019) ("[w]e have consistently rejected theories that the vaccine only "likely caused" the injury and reiterated that a "plausible" or "possible" causal theory does not satisfy the standard"); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Broekelschen v. Sec'y of Health & Hum. Servs*., 618 F.3d 1339, 1350 (Fed. Cir. 2010). This is consistent with the petitioner's ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted). If a claimant must *overall* meet the preponderance standard, it is logical that they be required also to meet each individual prong with the same degree of evidentiary showing (even if the *type* of evidence offered for each is different).

Petitioners may offer a variety of individual items of evidence in support of the first *Althen* prong, and are not obligated to resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). No one "type" of evidence is required. Special masters, despite their expertise, are not empowered by

statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Andreu,* 569 F.3d at 1380. Nevertheless, even though "scientific certainty" is not required to prevail, the individual items of proof offered for the "can cause" prong must *each* reflect or arise from "reputable" or "sound and reliable" medical science. *Boatmon,* 941 F.3d at 1359–60.

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Health & Hum. Servs.*, No. 06–522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356–57 (2011), *aff'd without opinion*, 475 F. App'x. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the

phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11–355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Standards Applicable to Significant Aggravation Claim*

Where a petitioner alleges significant aggravation of a preexisting condition, the *Althen* test is expanded, and the petitioner has additional evidentiary burdens to satisfy. *Loving v. Sec'y of Health & Hum. Servs*., 86 Fed. Cl. 135, 144 (2009). In *Loving*, the Court of Federal Claims combined the *Althen* test with the test from *Whitecotton v. Sec'y of Health & Hum. Servs.*, 81 F.3d 1099, 1107 (Fed. Cir. 1996), which related to on-Table significant aggravation cases. The resultant "significant aggravation" test has six components, which require establishing:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a "significant aggravation" of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving, 86 Fed. Cl. at 144; *see also W.C.*, 704 F.3d at 1357 (holding that "the *Loving* case provides the correct framework for evaluating off-table significant aggravation claims"). In effect, the last three prongs of the *Loving* test correspond to the three *Althen* prongs.

In *Sharpe v. Sec'y of Health & Hum. Servs.,* 964 F.3d 1072 (Fed. Cir. 2020), the Federal Circuit further elaborated on the *Loving* framework. Under Prong (3) of the *Loving* test, the Petitioner need not demonstrate an *expected* outcome, but merely that her current-post vaccination condition was worse than pre-vaccination. *Sharpe*, 964 F.3d at 1081. And a claimant may make out a prima facie case of significant aggravation overall without eliminating a preexisting condition as the potential cause of her significantly aggravated injury (although the Circuit's recasting of the significant aggravation standard still permits Respondent to attempt to establish alternative cause,

where a petitioner's showing is enough to make out a prima facie case and thereby shift the burden of proof to Respondent). *Id.* at 1083.

C. *Law Governing Analysis of Fact Evidence*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also*

Murphy v. Sec'y of Health & Hum. Servs., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are automatically deemed accurate, or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral and written testimony may be more persuasive than records, especially if the records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

D. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs*., 219 F.3d 1357,

1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). Under *Daubert*, the factors for analyzing the reliability of testimony are:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

However, in the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings—e.g., the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs*., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs*., No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters

must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

E. *Consideration of Medical Literature*

Both parties filed medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioners' case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

F. *Disposition of Case Without Hearing*

I am resolving this claim on the papers, rather than by holding a hearing. This is consistent with the determination of the prior special master to whom the case was assigned, and the parties have not in their filings opposed this mechanism for resolution. *See* Docket Entry, dated October 21, 2020. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. Servs.,* No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs*., 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Ct. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

I. Treatment of Hearing Loss Claims in Vaccine Program

SNHL is a kind of acute hearing loss, and a symptom of a prior disease or pathologic process. It therefore can have different potential etiologies, as both experts have acknowledged. First Tornatore Report at 5–7; First Bigelow Report at 9.

Program claimants have frequently argued that SNHL was attributable to a vaccine—but more often than not have *not* succeeded.[20] *See, e.g.*, *Inamdar v. Sec'y of Health & Hum. Servs.*, No. 15-1173V, 2019 WL1160341, at *16 (Fed. Cl. Spec. Mstr. Feb. 8, 2019) (referencing multiple prior negative decisions involving SNHL or hearing loss); *Donica v. Sec'y of Health and Hum. Servs.*, No. 08-625V, 2010 WL 3735707, at *1, 10 (Fed. Cl. Spec. Mstr. Aug. 31, 2010) (flu vaccine not demonstrated to cause adult hearing loss); *Hopkins v. Sec'y of Health & Hum. Servs.* Nos. 00-745V & 00-746V, 2007 WL 2454038, at *13 (Fed. Cl. Spec. Mstr. Aug. 10, 2007) (specific onset of hearing loss in child siblings after receipt of several vaccines could not be established; criticizing Dr. Tornatore's opinion as lacking foundation). In most such cases, the *fact* of post-vaccination SNHL was not disputed, but the claimants could not demonstrate the vaccine was causal.

In *Inamdar,* for example (a case I recently decided), a petitioner argued that the flu vaccine had caused SNHL, with onset the following day, based on two theories. *Inamdar,* 2019 WL1160341, at *5. First, the claimant argued that the vaccine "could cause the production of proinflammatory cytokines immediately upon vaccine administration." *Id.* But I determined that this argument relied too heavily on what was known about the wild virus rather than the vaccine. *Id.* at *6. The second theory was that specific components of the vaccine "were structurally homologous with ganglioside receptors on the neuronal myelin contained in the inner ear tissue, and that antibodies generated in response to the vaccine could also cross-react with the self myelin, resulting in tissue damage." *Id.*

I found, however, that this contention misapplied mechanisms relevant in other contexts. I also ruled that an alternative cause for the SNHL (the fact that the claimant was receiving

[20] Decisions from different cases do not control the outcome herein, with only Federal Circuit decisions setting legal standards to which new claims must adhere. *Boatmon v. Sec'y of Health & Hum. Servs*., 941 F.3d 1351, 1358-59 (Fed. Cir. 2019); *Hanlon v. Sec'y of Health & Hum. Servs*., 40 Fed. Cl. 625, 630 (1998). Nevertheless, special masters reasonably draw upon their experience in resolving Vaccine Act claims. *Doe v. Sec'y of Health & Hum. Servs*., 76 Fed. Cl. 328, 338-39 (2007) ("[o]ne reason that proceedings are more expeditious in the hands of special masters is that the special masters have the expertise and experience to know the type of information that is most probative of a claim") (emphasis added). They would thus be remiss in ignoring prior cases presenting similar theories or factual circumstances, along with the reasoning employed in reaching such decisions.

antibiotics at the time) existed, as well as that the short onset was not preponderantly defended. *Inamdar,* 2019 WL1160341, at *19. A too-short onset has been a notable obstacle to recovery in other cases. *See, e.g.*, *Donica,* 2010 WL 3735707, at *13 (two-hour post-vaccination onset of SNHL not demonstrated to be medically acceptable).

A more recent case involving SNHL, by contrast, resulted in a determination favorable to a petitioner, suggesting that there may well be reliable science (not previously considered or proposed in older cases) to support the contention that a vaccine could cause this kind of abrupt hearing loss. *See Madigan v. Sec'y of Health & Hum. Servs.*, No. 14-1187V, 2021 WL 3046614, at *1, 4 (Fed. Cl. Spec. Mstr. June 25, 2021) (flu vaccine caused adult petitioner's SNHL). But close consideration of the facts of that case reveals that *Madigan* is unhelpful to Petitioner herein. In *Madigan*, the petitioner's symptoms arose between *three to four days* post-vaccination. *Madigan,* 2021 WL 3046614, at *4, 20. Thus (and putting aside the additional fact that the causal theory offered therein is distinguishable from what was offered in this case), *Madigan* does not counsel in favor of a finding of causation in a case presenting an extremely short onset—such as the present matter.

II. Petitioner's Significant Aggravation Claim Has Not been Preponderantly Established

It is undisputed that Mr. Kelly began to experience severe hearing loss in his left ear within 30 minutes to two hours of his receipt of the flu vaccine. Ex. 2 at 18; Ex. 4 at 12. Thus, the primary question presented in this case is whether the flu vaccine *could* prompt such hearing loss—here, by exaggerating a preexisting asymptomatic microvascular angiopathy. But that question presupposes there *was* a preexisting condition subject to exaggeration—the first *Loving* prong. Accordingly, a preliminary issue to resolve in this case is whether Mr. Kelly in fact suffered from a preexisting but undiagnosed vascular condition.

A. Petitioner's Argument that He Suffered from a Preexisting Condition is Speculative and Unsupported by the Medical Record

The record does not preponderantly establish Petitioner's contention that he suffered from a preexisting microvascular angiopathy. Indeed, some of the evidence offered for this assertion provides particularly weak support. For example, the fact that Mr. Kelly was receiving a statin (a medication used prophylactically to arrest the development of hyperlipidemia) at the time of vaccination is hardly evidence that he suffered from any pre-vaccination vascular problem. Nor does the imaging evidence in this case corroborate Petitioner's contention. The initial scanning and imaging performed on Petitioner at the ER revealed little (beyond possible "small vessel ischemic changes") that could explain or undergird his hearing loss. Ex. 2 at 16, 30, 32, 89, 92. This scanning evidence was not deemed significant by contemporaneous treaters. And the initial

MRI was also inconclusive (although it was not admittedly completed).

Then, a repeat MRI performed in 2019 (apparently in an effort to bulwark this claim) revealed no more than "small ischemic changes," that again were not characterized as significant (or as evidence of a problem of the magnitude suggested by Petitioner). Ex. 35 at 1. In discussing this kind of evidence, Dr. Bigelow (who was demonstrably more qualified to opine on the causes and nature of hearing loss, given his actual medical focus and expertise, than Dr. Tornatore) persuasively established that not only was Petitioner's initial MRI incomplete (and thus could not be cited to confirm Petitioner's contention), but in fact the imaging and scanning overall did not establish the presence of the degree of vascular problems argued by Dr. Tornatore. First Bigelow Rep. at 5–7; Second Bigelow Rep. at 3. Dr. Bigelow also convincingly explained how the imaging would either likely reveal the kinds of preexisting issues that Dr. Tornatore maintained could not be displayed, or would at least have done so by the second time around (i.e. the 2019 MRI), assuming that the initial hearing loss had been attributable to an arterial occlusion in the ear. Second Bigelow Rep. at 3; Bigelow Resp. at 2.

Otherwise, Petitioner was never diagnosed with any vascular condition, there is no record evidence that he had any such problems prior to vaccination, there were no neurologic findings that would corroborate a vascular-oriented injury, and none of the post-vaccination records suggested Petitioner's SNHL had anything to do whatsoever with a preexisting vascular condition. Articles like Belal or Lee helped identify the kinds of clinical findings that would be consistent with preexisting arterial occlusion—but which are absent from this record. It simply cannot be concluded on this record that the purported preexisting condition—the admitted foundation for Dr. Tornatore's opinion—has been preponderantly established.

B. Petitioner Cannot Meet the Other *Loving* Prongs[21]

Respondent has questioned why Petitioner advances a significant aggravation claim, since the "condition" Petitioner arguably suffered from was not *itself* directly made "worse," but

[21] Because a claimant must establish all prongs of either *Althen* or *Loving* to prevail, my determination that Petitioner failed in so doing means I need not address each individual prong in my analysis. *de Bazan*, 539 F.3d at 1352. I will note, however, that the record does not preponderantly establish that Petitioner's SNHL was caused by the flu vaccine—and hence he did not meet *Althen* prong two/*Loving* prong five. There is little to no treater support associating the vaccine with Mr. Kelly's hearing loss beyond some statements by Dr. Reichman—and those statements need not be accepted at face value given their speculative character. *Snyder*, 88 Fed. Cl. at 746 n.67. The record otherwise provides no corroborative evidence that Petitioner *did* experience a hypersensitivity reaction to the vaccine, and testing and scanning/imaging performed on Petitioner did not produce results consistent with the proposed causal theory. And I give some weight as well to Respondent's contention that the alleged autoimmune mechanism of injury is rebutted by the fact that Petitioner did not see improvement from the kinds of steroidal treatments usually effective in addressing autoimmune illness, thus undermining the evidentiary support for that mechanism as an alternative.

instead was merely the purported causal foundation for the true injury of hearing loss. Opp. at 19. In Respondent's view, Petitioner could just as easily have styled his claim as a regular non-Table, causation-in-fact claim, alleging that the flu vaccine caused his SNHL (in the vascular-Type I sensitivity manner alleged). There was no need to invoke *Loving* at all.

I am addressing the claim as pled, in acknowledgement of a petitioner's right to define the claim he wishes to assert. But I also note that since the *Loving* prongs incorporate the three *Althen* prongs, my determination would be the same even if this case had more simply alleged that the flu vaccine precipitated hearing loss by unmasking or negatively interacting with an otherwise-benign and asymptomatic condition. Because whether the claim arises under *Loving* or not, it founders on the first and third *Althen* prongs—*Loving* prongs four and six.

1. *Petitioner's Onset is Entirely Too Short (Loving Prong Six)*

In addition to the fact that no preexisting vascular condition has been demonstrated on this record, the claim also fails because Petitioner's onset was entirely too short to be deemed medically acceptable.

Although the Program recognizes that sensitivity/allergic reactions to vaccination exist, and can manifest abruptly (with anaphylaxis being the best example[22]), the evidence offered in this case does not preponderantly support the conclusion that the flu vaccine could prompt acute hearing loss so quickly, under the causal mechanism(s) proposed herein. Even if I accepted Petitioner's analogy of the hearing loss that occurred herein to Meniere's, the evidence offered relating to the latter in support of a short onset timeframe, like Takeda, distinguished the time for *reaction* from the time of actual hearing loss, as Respondent has pointed out. Opp. at 25–26; Takeda at 888–89.

Petitioner's timing contentions otherwise raise far more questions than they persuasively resolves. How would the introduction of antigens from the flu vaccine in a peripheral part of the body cause an IgE allergic/hypersensitivity reaction within the ear less than two hours later—and without evidence of a similar/related reaction spatially close to the situs of vaccination? Comparisons to Meniere's disease (which does not characterize what Petitioner experienced) were not enough to preponderantly establish the point, especially since the nature of injury alleged (vascular in origin) was distinguishable from what is known about how Meniere's occurs. The mere existence of *other* Type I hypersensitivity reactions in medicine, and the fact that they can occur quickly, does not make it even barely plausible that SNHL due to vaccination

[22] The Vaccine Injury Table recognizes anaphylaxis and anaphylactic shock for "[m]easles, mumps, rubella, or any vaccine containing any of the forgoing as a component; DT; Td; or Tetanus Toxoid," and "[i]nactivated polio vaccine," and requires a claimant to establish post-vaccination onset in four hours or less. 42 U.S.C. § 300aa-14.

could proceed in so swift a manner.

In addition, an autoimmune mechanism for injury in this case (which to some extent stands as an alternative causation mechanism) would not likely occur in so fast a timeframe. If Petitioner's SNHL was autoimmune in nature, involving the production of IgE by B cells (as Dr. Tornatore alleges (First Tornatore Rep. at 7)) how would an adaptive immune response (which is what in most cases drives autoimmunity)—a process that the Program recognizes can take *days* to unfold—occur so rapidly? *Pelelo v. Sec'y of Health of Hum. Servs.*, No. 17-1485V, 2021 WL 4100312, at *20 (Fed. Cl. Spec. Mstr. Aug. 6, 2021) (discussing timeframe for adaptive immune response in the context of peripheral neuropathy). It is true that the initial, innate response to vaccination results in a comparatively-faster release of a variety of immune cells, including cytokines—but an autoimmune response involving antibody production would not occur in so short a timeframe. Even a case report filed by Dr. Bigelow, Huang, relating to hearing loss after the flu vaccine involved a timeframe of no less than *14 hours*. Huang at 850.

Dr. Tornatore endeavored to respond to these questions, but he did not do so in a manner that exceeded a bare showing of plausibility. There is inadequate evidence in this record, or contained in Dr. Torntore's expert reports, that would permit me to conclude that (even assuming the flu vaccine *generally* could cause SNHL in the manner alleged) onset of less than two or even three hours is medically acceptable.

2. *Petitioner has not Preponderantly Established the Flu Vaccine Could Cause SNHL (Loving Prong Four)*

The evidence offered for the "can cause" prong (evaluated by the same standard, whether the claim is analyzed under *Althen* prong three or *Loving* prong four) also failed to clear the preponderant line. Ultimately, Dr. Tornatore's opinion unsuccessfully attempted to combine a number of different components, not all of which meshed together, and which did not collectively add up to a persuasive showing.[23]

Of the mechanisms proposed as potentially causal, the one Dr. Tornatore seemed to end up favoring was that Petitioner experienced a rapid Type I sensitivity reaction that could exacerbate a vascular condition in Petitioner's ear. Tornatore Rep. at 1, 4. There were individual aspects of this theory that were reliable, such as the concept that vaccines can cause *other*

[23] Although Dr. Tornatore's theories were argued in the alternative, they were also somewhat inconsistent. Thus, the idea that flu vaccine could cause an autoimmune response contradicted the concurrent argument that the flu vaccine could prompt an allergic, Type I sensitivity reaction, since an autoimmune process could not be mediated in so short a timeframe.

hypersensitivity reactions, or that *distinguishable* ear-oriented illnesses (like Meniere's) can result in hearing loss due to antigenic stimulation. *See, e.g.*, Topuz. But the theory *here* not only required a finding that Petitioner possessed a pre-existing vascular condition subject to exacerbation (something I have not found was preponderantly demonstrated), but also that the flu vaccine could worsen that condition by the same mechanism applicable to a different kind of illness.

In addition, the evidence connecting the flu vaccine specifically to SNHL as a general matter was limited to nonexistent. At most, Petitioner offered a few case reports—a kind of evidence warranting low probative weight. *R. V. v. Sec. of Health & Hum. Servs.*, No. 11-504V, 2016 WL 3882519, at *41 (Fed. Cl. Spec. Mstr. Feb. 19, 2016) ("individual patient case reports... are not, in general strong evidence of causation" (internal quotation marks omitted)), *mot. for rev. denied,* 127 Fed. Cl. 136 (2016). By contrast, reliable epidemiologic articles, like Baxter, found no increased risk for post-flu vaccine SNHL. Baxter at 83, 85. As the Federal Circuit has observed, although petitioners are *never* required to offer their own supportive epidemiologic evidence to prevail, it can be evaluated and given weight when it exists—and it can undermine a petitioner's causation showing. *D'Tiole v. Sec'y of Health & Hum. Servs.*, 726 F. App'x 809, 811–12 (Fed. Cir. 2018).[24] Otherwise, the potentiality for homology between amino acid sequences in the vaccine's antigens and tissues in the ear was not enough to show that the flu vaccine (or the underlying wild virus it seeks to protect against) would *likely* cause a cross-reaction in the ear, resulting in hearing loss.

The contention that SNHL could be driven by an autoimmune process, argued in the alternative, was inconsistent with the timeframe in which Petitioner's hearing loss actually presented—as well as the fact that autoimmune-caused hearing loss would more likely present bilaterally. Second Bigelow Rep. at 3–5. It was no answer to say that "sometimes" this was what happened. Indeed, Dr. Bigelow persuasively established that hearing loss with a vascular origin would similarly progress to a more complete loss. And an autoimmune origin would in most

[24] Dr. Tornatore also attempted to drain Baxter of the weight I am giving it by maintaining that the "rare" nature of a vaccine injury means that almost any large-scale epidemiologic study will be inadequately powered to detect the event. *See, e.g.*, Second Tornatore Rep. at 14–15. But this argument (ignoring the fact that it is contrary to the Federal Circuit's stated position on the relevance of this kind of evidence in Vaccine Program cases) is nonsensical. The fact that a large-scale study can never with certainty *disprove* the possibility of causation by vaccine does not mean it lacks evidentiary weight capable of undermining the petitioner's showing (and of course it is the *petitioner's burden* to make that showing—not Respondent's to prove a negative). A trustworthy epidemiologic study can undermine a Petitioner's case, even if it cannot make the causal claim impossible.

Moreover, it is logically inconsistent for petitioners to categorically dismiss the evidentiary import of contrary epidemiologic evidence—but in the same breath tout the significance of case reports (which Program petitioners do all the time). If case reports (usually involving only a handful of impacted/vaccinated individuals) have any evidentiary value in proving a causal association, why would a study involving thousands if not millions of vaccine recipients not *also*?

cases mean some *other* underlying systemic disease was occurring—again, absent from this record

In reaching the conclusions I do on the insufficiencies in Petitioner's causation theory, I have overall given Dr. Tornatore's opinion less weight than the rejoinder offered by Dr. Bigelow. Dr. Tornatore was generally qualified to testify on many of the immunologic issues in contention, and (as noted) individual aspects of his opinion made plausible contentions or had some reliable scientific basis. But he plainly does not possess the otolaryngologic expertise of Dr. Bigelow. Respondent's expert simply displayed a better working understanding of the foundations of hearing loss and its possible causes, he explained why the causation theories offered were insufficient, and he more credibly interpreted the record in this case.

III. This Case was Properly Resolved Without a Trial

In ruling on the record, I am choosing not to hold a hearing. Determining how best to resolve a case is a matter that lies generally within my discretion, and although the parties have not objected to this method of adjudication, I shall explain why a hearing was not required.

Prior decisions have recognized that a special master's discretion in deciding whether to conduct an evidentiary hearing "is tempered by Vaccine Rule 3(b)," or the duty to "afford[] each party a full and fair opportunity to present its case." *Hovey*, 38 Fed. Cl. at 400–01 (citing Rule 3(b)). But that rule also includes the obligation of creation of a record "sufficient to allow review of the special master's decision." *Id*. Thus, the fact that a claim is legitimately disputed, such that the special master must exercise his intellectual faculties in order to decide a matter, is not itself grounds for a trial (for if it were, trials would be required in every disputed case). Special masters are expressly empowered to resolve fact disputes without a hearing—although they should only so act if a party has been given the proper "full and fair" chance to prove their claim.

The present claim could be, and was, resolved fairly without the need for live testimony from the experts. The SNHL injury was not disputed, nor the facts pertaining to its onset, leaving only the causation theory and the alleged preexisting condition to be determined. The parties engaged in several rounds of expert report submissions, allowing a fairly well-developed record on the disputed issues—and both experts honed their opinions over time, as they reacted to criticisms lodged by their counterpart or answered questions posed by the special master previously presiding over this action. These reports, and the articles filed in support, provided me with all that was required to ascertain entitlement in this case—live testimony from the experts would not have altered the outcome, as I could understand the nature of the experts' disagreement based on the written record itself. Petitioner otherwise had ample opportunity to substantiate his claim, as the number of reports filed herein establishes.

CONCLUSION

This claim is dismissed. In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accord with this decision.[25]

IT IS SO ORDERED.

s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[25] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.